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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,218	01/28/2002	Arne Holmgren	P21480	8453
7055	7590	05/31/2006	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			KUMAR, SHAILENDRA	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,218	HOLMGREN ET AL.	
	Examiner	Art Unit	
	SHAILENDRA - KUMAR	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 July 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 13-25 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 13-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/28/05 9/28/05</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to Board's decision rendered on 7/29/05.

The Board reversed the examiner's rejection based on 35 USC 103, and has raised a new issue as follows:

"It appears from the record that ebselen has been known in the art for some time as an anti-oxidant, and may have been administered in vivo prior to the effective filing date of the present application. It is not clear from the record whether appellants and the examiner have determined whether or not this is the case, and if so, whether administration of ebselen in vivo inherently results in the activities required by the claims."

In view of the above, the prosecution is reopened and following office action is in order.

Claims 13-25 are pending in this application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 9/28/05 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 13-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Welter et al(US 4,418,069) or Dereu et al(US 4,730,053), or EP 0 366 990, or CA 02276984, or WO 9726968.

Instant claims are directed to a method for reduction of a substrate with thioredoxin reductase, comprising combining the thioredoxin reductase, the substrate and NADPH under conditions to reduce the substrate, the substrate comprising a substance selected from the group consisting of a compound represented by the general formula (1) or (1') of claim 13 and a physiologically acceptable salt thereof, and a hydrate thereof and a solvate thereof.

Welter et al teach administration in vivo of structurally similar compounds as claimed herein for treating arthritis, see the abstract for the compounds structure and column 4, lines 47-65 for the administration, or Dereu et al, teach administration of ebselen in vivo for treating injury, see abstract and column 3-column 4, or EP'990 teach administration of ebselen in vivo for treatment of numerous diseases, see page 2, 2nd paragraph, or CA'984, teach in vivo administration of ebselen for treating asthma, see the abstract, or WO'968 teach in vivo administration of ebselen for treating ischemic diseases, see the abstract and page 1. Inasmuch as the ebselen is administered in vivo, instant claims are anticipated in terms of reduction method, as thioredoxin reductase and NADPH are all part of the in vivo component, see Board's remarks, supra.

Claim Rejections - 35 USC § 103

3. Claims 13-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of Bjornstedt et al(JBC, 1995), Kumar et al(Eur. J. Biochem, 1992) and Arteel et al(Chem. Res. Toxicol, 1999).

Instant claims are directed to a method for reduction of a substrate with thioredoxin reductase, comprising combining the thioredoxin reductase, the substrate and NADPH under conditions to reduce the substrate, the substrate comprising a substance selected from the group consisting of a compound represented by the general formula (1) or (1') of claim 13 and a physiologically acceptable salt thereof, and a hydrate thereof and a solvate thereof

Bjornstedt et al teach a method for reduction of a substrate with thioredoxin reductase, comprising combining the thioredoxin reductase, the substrate and NADPH under conditions to reduce the substrate, the substrate being Selenocystein instead of compounds claimed in herein and one of them being ebselen, see page 11761.

Likewise, Kumar et al, teach a method for reduction of a substrate with thioredoxin reductase, comprising combining the thioredoxin reductase, the substrate and NADPH under conditions to reduce the substrate, the substrate being selenite instead of ebselen as claimed herein, see page 435.

Arteel is teaching that activity of selenocystein and ebselen are similar when oxidation of thioredoxin is concerned that is they get reduced in the same manner, and it will be expected that selenite and ebselen will behave the same way, see page 264, because selenium is known to be reducing agent in the chemical art. Thus claimed

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method is no more than a mere combination and variation of prior art teachings, absent evidence to the contrary.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAILENDRA - KUMAR
Primary Examiner
Art Unit 1621

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4/25/06



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